REMARKS

Claim 10 has been amended as it had been intended to be amended in the Preliminary Amendment filed August 19, 2000 and now recites language that does not conflict with the original language. It is submitted that claims 11 and 12 are now appropriate.

Claims 2 and 3 have been amended in response to the rejection under 35 USC 112, second paragraph.

Claims 1, 7, 8, 9 and 10 have been amended to make it explicit that the predetermined amount of the subsidiary dose is less than the first dose.

The invention, as claimed in independent claims 1, 9 and 10, relates to a device and method that provides a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsididary dose with the primary dose to provide a variable dose.

The claims have been rejected on the basis of Gottenauer DE 44 00 084, which shows an inhaler with twenty-eight independently openable containers of medicament. In the office action it is stated that the containers are "fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers." This statement is in error as a matter of law. Whether prior art is capable of something is irrelevant unless it discloses, teaches or at least suggests that feature. As noted in the MPEP 2143.03: "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)."

Here there is no disclosure, teaching or suggestion in Gottenauer of the claim limitation of the subsidiary dose being less than the primary dose, as is required by all independent claims. The independent claims accordingly are not rendered obvious by Gottenauer, and the independent claims are allowable under 35 USC 103(a).

The remaining claims, including claims 11 and 12, depend on the independent claims and are allowable with them.

The claims have also been rejected for obviousness type double patenting on the basis of Kallstrand U.S. Patent No. 5,533,505. That patent only shows, and claims, a device with a single

compartment. The claims herein require, in addition, a further compartment with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsididary dose with the primary dose to provide a variable dose. This is nowhere suggested by the '505 patent, and the rejection should be withdrawn.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a $110 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 11, 2001

William E. Booth
Reg. No. 28,933

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20285510.doc

Version with markings to show changes made

In the claims:

Claim 1, 2, 3, 7, 8, 9, 10 have been amended as follows:

1. (Twice Amended) A single use inhaler for administering medicament by inhalation, the inhaler comprising:

an inhalation channel through which a user may inhale;

a first container for containing a first dose of medicament; and

a first release means for releasing said first dose into the said inhalation channel; wherein the inhaler further comprises:

at least one subsidiary container for containing a subsidiary dose of medicament;

at least one respective subsidiary release means for releasing said subsidiary dose into said inhalation channel; wherein

said first release means is independently operable of said at least one subsidiary release means such that one or more of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided and the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose.

2. (Twice Amended) An inhaler according to claim 1 wherein said first container and said at least one subsidiary container are integral parts of the inhaler.

3. (Twice Amended) An inhaler according to claim 2 wherein said first container and said at least one subsidiary container comprise depressions in at least one wall of said inhalation channel and said release means and said subsidiary release means respectively comprise films sealing said depressions.

7. (Twice Amended) An inhaler according to claim 1 wherein the inhaler comprises at least two subsidiary containers and the subsidiary dose of each of said at least two subsidiary containers is a predetermined fraction of said first dose that is less than said first dose.

8. (Twice Amended) An inhaler according to claim 7 wherein said subsidiary doses include different predetermined fractions of said first dose that are less than said first dose.

9. (Twice Amended) A method of providing a variable dose in a single use inhaler having an inhalation channel through which a user may inhale, a first container for containing a first dose of medicament and a first release means for releasing said first dose into said inhalation channel, said method comprising;

providing at least one subsidiary container in said single use container for containing a subsidiary dose of medicament whereby the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose;

providing at least one respective subsidiary release means for releasing said subsidiary dose of medicament into said inhalation channel; and

arranging for said first release means to be independently operable of said subsidiary release means such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided.

10. (Amended) A method of providing a variable quantity of substance in a channel of an administration device, comprising the steps of;

opening a first container containing a first dose of said substance and dispensing said substance in said channel;

selectively opening a subsidiary [second] container containing a subsidiary dose of said substance according to the total quantity of substance required and dispensing said substance in said channel wherein said subsidiary container contains an amount of said substance which is a predetermined fraction of the amount of the substance contained in the first container that is less than said first dose.